



The University of
Nottingham



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PHYSIOTHERAPY MANAGEMENT OF URINARY INCONTINENCE IN ATHLETIC WOMEN- A FEASIBILITY STUDY

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Short title: Physiotherapy to treat Urinary Incontinence in Athletes

Acronym: POsITlve

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Research Council**



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STUDY PERSONNEL AND CONTACT DETAILS

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SYNOPSIS

Title	Physiotherapy Management Of Urinary InconTinenCe In Athletic Women – a feasibility study
Acronym	POsITlve
Short title	Physiotherapy to treat Urinary Incontinence in Athletes
Chief Investigator	Dr Gillian Campbell (Daphne Jackson Research Fellow, University of Nottingham)
Objectives	To assess the feasibility of conducting a randomised controlled trial of physiotherapeutic intervention in the management of urinary incontinence in athletic women
Study Configuration	Single centre
Setting	Local community
Number of participants	Phase 1: 6-8 local health professionals Phase 2: 15-20 athletic women recruited from local sports clubs and gyms Phase 3: 6-8 of the participants from phase 2
Eligibility criteria	Phase 1: <ul style="list-style-type: none"> G.P.s, Nurses, Physiotherapists from the Nottinghamshire and Derbyshire area Phase 2: <ul style="list-style-type: none"> Female 18 years and over Currently exercising three times and for over 150 minutes per week Self-reported symptoms of urinary incontinence including urinary frequency and increased urinary urge No ongoing or recent intervention for treatment of UI Phase 3: <ul style="list-style-type: none"> Purposeful selection of a range of participants from phase 2
Description of interventions	Phase 1: <ul style="list-style-type: none"> Local healthcare professionals will be interviewed to establish general management of UI in athletic women



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	<p>Phase 2:</p> <ul style="list-style-type: none"> • All participants will complete a sporting log, questionnaires ICIQ, UDI 6 and a fluid chart • Participants will undergo a subjective and objective physiotherapy assessment • A pelvic floor muscle rehabilitation plan will be agreed and participants will attend for physiotherapy, education and advice for up to 7 interventions over 6 months • At 3 months and 6 months participants will repeat questionnaires ICIQ, UDI 6 and a further fluid chart • Participants will be discharged from treatment or, if still symptomatic, referred, if they wish, for ongoing care <p>Phase 3:</p> <ul style="list-style-type: none"> • Participants will be purposefully selected from phase 2 for qualitative interviews in order to obtain information about their reactions to phase 2 and in depth data regarding how their symptoms have impacted on their life and any previous attempts to address their symptoms
Duration of study	<p>Overall: 01/05/19 – 31/09/20</p> <p>Per participant:</p> <p>Phase 1 participants – up to 30 minutes</p> <p>Phase 2 participants – up to 6 months</p> <p>Phase 3 participants – up to 30 minutes</p>
Methods of analysis	<p>Qualitative data will be analysed thematically</p> <p>Quantitative data will be analysed using descriptive statistics</p>



ABBREVIATIONS

UI	Urinary Incontinence
AE	Adverse Event
CI	Chief Investigator overall
CRF	Case Report Form
PFM	Pelvic Floor Muscles
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
REC	Research Ethics Committee
R&D	Research and Development department
SAE	Serious Adverse Event
UoN	University of Nottingham
MRC	Medical Research Council
HCP	Health Care Professional
CSP	Chartered Society of Physiotherapy
HCPC	Health and Care Professions Council



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STUDY BACKGROUND INFORMATION AND RATIONALE

Urinary incontinence (UI) is defined as including symptoms of involuntary loss of urine associated with change of position, impact or urgency and to include increased urinary urgency and increased daytime frequency (Haylen et al., 2010). This is a widespread problem in adult women, with prevalence being reported in the UK as high as 40% (Cooper et al., 2015). It is both embarrassing and debilitating for those affected, impacting on all aspects of life. There is evidence that it reduces participation in sports and exercise (Brown and Miller, 2001, Nygaard et al., 2005, Menezes, 2015), affects employment, causes absence from the workplace (Fultz et al., 2005) and is detrimental to personal relationships (Nilsson et al., 2009). Generally it is accepted that UI is associated with childbirth, obesity and the ageing process (Danforth et al., 2006, Kuh et al., 1999). As such it is assumed that a primary cause is weakness of the pelvic floor muscles (PFM).

UI is particularly common in athletic and sporting women and has been reported as being almost double that in a matched group of sedentary counterparts (Carvalhais et al., 2018). Investigations into UI in athletes reveals varying prevalence ranging from 23 – 41% (Alves et al., 2017, Bo et al., 2011, Carls, 2007, Jacome et al., 2011). Generally these studies involved young, nulliparous athletes. An investigation into recreationally active women revealed much higher numbers of 49%, although this figure was only related to stress urinary incontinence (SUI) and did not allow for urgency or urge related incontinence (UUI) (McKenzie et al., 2016). This was an investigation of athletes with a large range of ages, 18 – 83, and parity which may explain the high prevalence compared with other studies of younger nulliparous women with fewer risk factors. Improving the strength and endurance of PFM is generally regarded the optimal first line in treatment. While there is evidence to support physiotherapy to treat UI in the general population (Bo et al., 1999, Dumoulin et al., 2004) and it is supported by NICE (NICE, 2013), there is little research regarding interventions in athletes, despite the high levels of UI in this population.

It has been suggested that there are two conflicting mechanisms for UI in athletic women:

- Athletes may have stronger pelvic floors than non-athletes due to the training effect of repeated impact
- the repeated challenge of ground reaction forces from running and jumping may serve to weaken and stretch the fascia and muscle tissues within the pelvis (Bo, 2004).

One possible explanation, which might allow for athletes having stronger pelvic floors but still presenting with UI, would be if the pelvic floor muscle was strong and stiff but inextensible i.e. unable to fully relax. An overactive PFM group would potentially be



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unable to react to ground reaction forces adequately. Increased PFM tension has been noted in cases of increased urinary urge and frequency with or without associated pelvic pain (Weiss, 2001). Assessment of some PFM can reveal areas within the tissue that are overactive or 'tight' (Aw et al., 2017). There is little published data regarding how prevalent this is or whether this is more likely in certain groups of women. It is, however, feasible that the athletic PFM may be dysfunctional rather than weak. In this case it would be imperative that there is an assessment by a specialist physiotherapist in order to identify the appropriate training and rehabilitation programme. Standard protocols advising general PFM strengthening with no tailored advice may not afford any real improvement and in some cases may, in fact, aggravate the symptoms.

There are few studies evaluating conservative management strategies in an athletic population (Da Roza et al., 2012, Ferreira et al., 2014) and while these have shown improvements, only the latter used a control group. It was also unclear from the methodology in this RCT, whether the rehabilitation was guided by any formal PFM assessment such as a digital vaginal assessment (DVE) or other forms of biofeedback. Despite the high prevalence of UI generally in women, less than half of these will present to health professionals for help (Cooper et al., 2015). This is an even bigger issue in athletes with UI where 90% of those with UI reported not mentioning their symptoms to anyone (Carls, 2007). It is important to rationalise why these women do not seek help and when they do ensure that they are offered effective, evidence based treatment.

This study is a first step to investigating what treatments are offered in the community to athletic women presenting with UI and to the acceptability and benefits of one to one specialist physiotherapy treatment within this patient group.



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STUDY OBJECTIVES AND PURPOSE

PURPOSE

Our overall purpose is to conduct an RCT to determine whether one to one physiotherapy can improve the symptoms of urinary incontinence (UI) in a group of athletic women. This feasibility study will enable us to ascertain the viability of conducting a definitive appropriately powered trial.

PRIMARY OBJECTIVES

The primary objective is to assess the feasibility of conducting a randomised controlled trial of physiotherapeutic intervention in the management of urinary incontinence (UI) in female athletes and those that exercise regularly.

This will involve gathering and analysing information regarding the eligibility criteria of the participants and data regarding recruitment. It will provide information about the consent procedures, outcome measures, the acceptability of the intervention, retention of participants and use the data to inform the determination of a sample size calculation for a definitive trial.

STUDY DESIGN

This is a mixed-methods study with three distinct but related phases.

In phase 1, six to eight local health care professionals (HCP) including general practitioners, nurses and physiotherapists, will be recruited for interview. This will explore current management practices of UI in the community to inform a future control group and to review current knowledge regarding specialist pelvic health physiotherapy.

In phase 2, participants who are sporting or athletic women, who self-report symptoms of UI, will be recruited from the local sporting community.

Urinary incontinence will be defined as any of the following:

- stress urinary incontinence (SUI), leaking of urine associated with increased abdominal pressure e.g. impact, coughing or sneezing
- urge urinary incontinence (UUI) leaking of urine associated with urinary urge, increased urinary urge and/or increased urinary frequency

Sporting or athletic women will be defined as those who exercise three or more times a week and for more than 150 minutes each week.



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Each participant will undergo individual subjective and objective assessments in order to establish history, symptoms and pelvic floor muscle function. The intervention will be then be tailored from these assessments, where upon participants will be enrolled into the intervention agreed between each individual and the specialist physiotherapist. This is likely to include guided exercise within the clinic and a regular home exercise plan and will be in keeping with typical rehabilitation regimes for PFM dysfunction within this specialist area. If appropriate, soft tissue release techniques may be used to reduce muscle spasm.

In phase 3, six to eight participants that take part in phase 2 will be offered the opportunity to take part in a qualitative interview in order to gain more in-depth understanding. The aim of the interviews will be to explore the acceptability of the intervention and the effects of UI on quality of life and participation in sport and exercise. We will purposefully select participants in order to account for age, sporting activity and severity of symptoms.

STUDY MANAGEMENT

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

A study steering group, comprising the co-investigators, two service user representatives and a specialist pelvic health physiotherapist, will oversee the study.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration:

Enrolment will begin in May 2019 and cease in March 2020.

The total duration of the study will be 18 months (excluding one month for write up and dissemination)

Participant Duration:

Phase 1: Approximately 30 minutes

Phase 2: Up to six months

Phase 3: Approximately 30 minutes



End of the Study

The final data collection will be 31st September 2020. The end of the study including analysis and dissemination will be 31st January 2021.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Phase 1

We will aim to recruit six to eight local health care professionals for interview to explore their knowledge of UI in athletic women and how they might manage these patients. They will be approached by email, through professional and personal contacts or via professional networks, e.g. Royal College of General Practitioners, Royal College of Nurses, and Chartered Society of Physiotherapy.

Phase 2

Participants will be athletic and sporting adult women who self-report urinary incontinence.

Urinary incontinence will be defined as any of the following: leaking of urine associated with increased abdominal pressure e.g. impact, leaking of urine associated with urinary urge, increased urinary urge and/or increased urinary frequency.

Athletic and sporting women will be defined as those who exercise over three times a week and for more than 150 minutes in total each week.

We aim to recruit 15 – 20 adult women from the Derbyshire and Nottinghamshire community via:

- Pelvic health presentations to local sports clubs and gyms
- Emails to local sports clubs and gyms
- Leaflets to local sports clubs and gyms
- Social media e.g. Facebook, Twitter

Phase 3

Six to eight of the participants from phase 2 will be purposefully recruited to be interviewed about their experience of phase 2 of this study, their experiences of UI and the effects on their quality of life and sporting participation and any previous experience they have had of treatment for UI. The selection will be purposeful in order to account for a range of ages, type and severity of UI and of primary sporting activity.



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Eligibility criteria

Inclusion criteria

Phase 1:

- Qualified local Health Care Professional eg G.P., nurse or chartered physiotherapist working within Nottinghamshire or Derbyshire.

Phase 2:

- Adult female
- Currently exercising for a minimum 3 times a week and for over 150 minutes per week
- Self-reported experience of symptoms of UI defined as; leaking of urine associated with increased abdominal pressure e.g. impact, leaking of urine associated with urinary urge, increased urinary urge and/or increased urinary frequency.

Phase 3:

- Participant in Phase 2, purposeful selection will be made to ensure a range of age, sporting activity and UI symptoms.

Exclusion criteria

Phase 1

- Unwilling or unable to provide written informed consent
- Not within Nottinghamshire or Derbyshire area
- Unable to read or speak English

Phase 2 and 3

- Under 18
- Sports participation less than 1 year
- Pregnancy
- Less than one year after childbirth
- Ongoing physiotherapy or continence advice treatment elsewhere or within the last year
- De novo oestrogen or anticholinergic treatment
- Existing neurological conditions that may contribute to UI eg multiple sclerosis, stroke, spinal injury etc
- Unwilling or unable to provide written informed consent
- Unable to read or speak English



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Expected duration of participant participation

Phase 1 participants	Up to 30 minutes
Phase 2 participants	01/05/19 – 31/09/20 (there will be up to 1 year of recruitment until 15 – 20 participants are enrolled: each intervention will be up to 6 months, so the last participant may be 31/03/20 – 31/09/20)
Phase 3 participants	Up to 30 minutes

Participant Withdrawal

In each of the study phases, participants may withdraw from the study either at their own request or be withdrawn at the discretion of the Investigator. Participants will be made aware (via the participant information sheet and consent form) that should they withdraw, the data collected cannot be erased and may still be used in the final analysis.

Participants who withdraw will be replaced if this is possible within the time frame of the study. The last participant will be recruited by 31/02/20.

Informed consent

All participants in Phases 1, 2 and 3 will provide written informed consent. The Consent Form will be signed and dated by the participant before they enter the study. The Investigator will explain the details of the study and provide a Participant Information Sheet (PIS), ensuring that the participant has a minimum period of 24 hours to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

In phase 2 there will be a separate written informed consent obtained for digital vaginal examination as is good practice in this physiotherapy speciality. At this stage the participant will be offered the opportunity for a chaperone to be present for the DVE. If they would like this but are unable to provide one then one will be provided by the research group. It will be noted in writing whether they have chosen to have a chaperone or not.

For all consent forms completed, one copy of the consent form will be kept by the participant and one will be kept by the Investigator.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended consent form which will be signed by the participant.



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STUDY REGIMEN

Phase 1

Participants will be recruited to take part in semi-structured interviews. These interviews will establish the type of advice and treatment routinely prescribed for this patient group. It will also explore the participant's previous knowledge of specialist pelvic health physiotherapy.

The interviews will be conducted face to face by a member of the research team and arranged at the convenience of the participant. The interviews will take place at a location convenient to the participant. Digital audio-recordings will be transferred to a secure and password protected file on a dedicated web server at the University of Nottingham. Personal identifiers will be removed. The recording will then be deleted from the recording device. Anonymised recordings will be sent electronically to a transcribing service approved by the University of Nottingham.

Phase 2

Following an expression of interest in the study, a participant information sheet will be sent, either via email or by post, and potential participants will be given 24 hours to read this prior to any appointments.

The researcher will then contact the potential participant, explain the study and answer any questions that the potential participant may have. If they are happy to proceed the researcher will arrange an appointment at a location to suit the participant. This will be either within the hospital site or at a clinic in the community.

At the first appointment the process of completing the study questionnaires, sporting log and fluid charts will be explained in greater detail. Written, informed consent will be taken prior to any data collection.

Questionnaires will include urinary symptoms eg the type and severity of their UI and the degree this impacts on their quality of life and their sporting participation.

The sporting log will record information regarding the time, intensity, type of sporting activity and any related incontinence episodes.

The fluid chart will be a three day record of all measured fluid input and output with any incontinence episodes noted. Two labelled jugs will be provided.

Questionnaires, sporting log and fluid chart will be collected at the second appointment with a specialist pelvic health physiotherapist. This will include a full subjective assessment recording their obstetric, gynaecological and past medical history.

An objective assessment is planned to include a digital vaginal examination (DVE) of pelvic floor function. Further written consent will be obtained in line with best practice



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in this field. If the participant is unwilling to have a DVE, they will be asked if they wish to continue with the questionnaires at 3 and 6 months. Those that agree to this will be issued with an advice leaflet and reviewed at 3 and 6 months but will have no other formal rehabilitation plan. Those that are unwilling to continue with data collection will be excluded from the study.

Participants will be asked if they wish a chaperone to be present for the DVE if they wish this to be the case but are unable to provide one, then one will be provided by the research study. The choice to have a chaperone or not will be noted in their file.

After the assessment DVE of the PFM, participants will be offered the opportunity for electromyographic (EMG) assessment of their PFM to establish the level of activity at rest and if function is altered in an upright position.

A tailored training plan will be agreed between the participant and the pelvic health physiotherapist depending on the results of the subjective and objective assessments. It is likely that this will include a home exercise plan, re-education of their pelvic floor contractions with EMG biofeedback in the clinic and lifestyle advice. If appropriate, soft tissue techniques may be used to reduce marked muscle spasm.

Objective assessments including the DVE, questionnaires and fluid charts will be repeated at 3 months and at 6 months.

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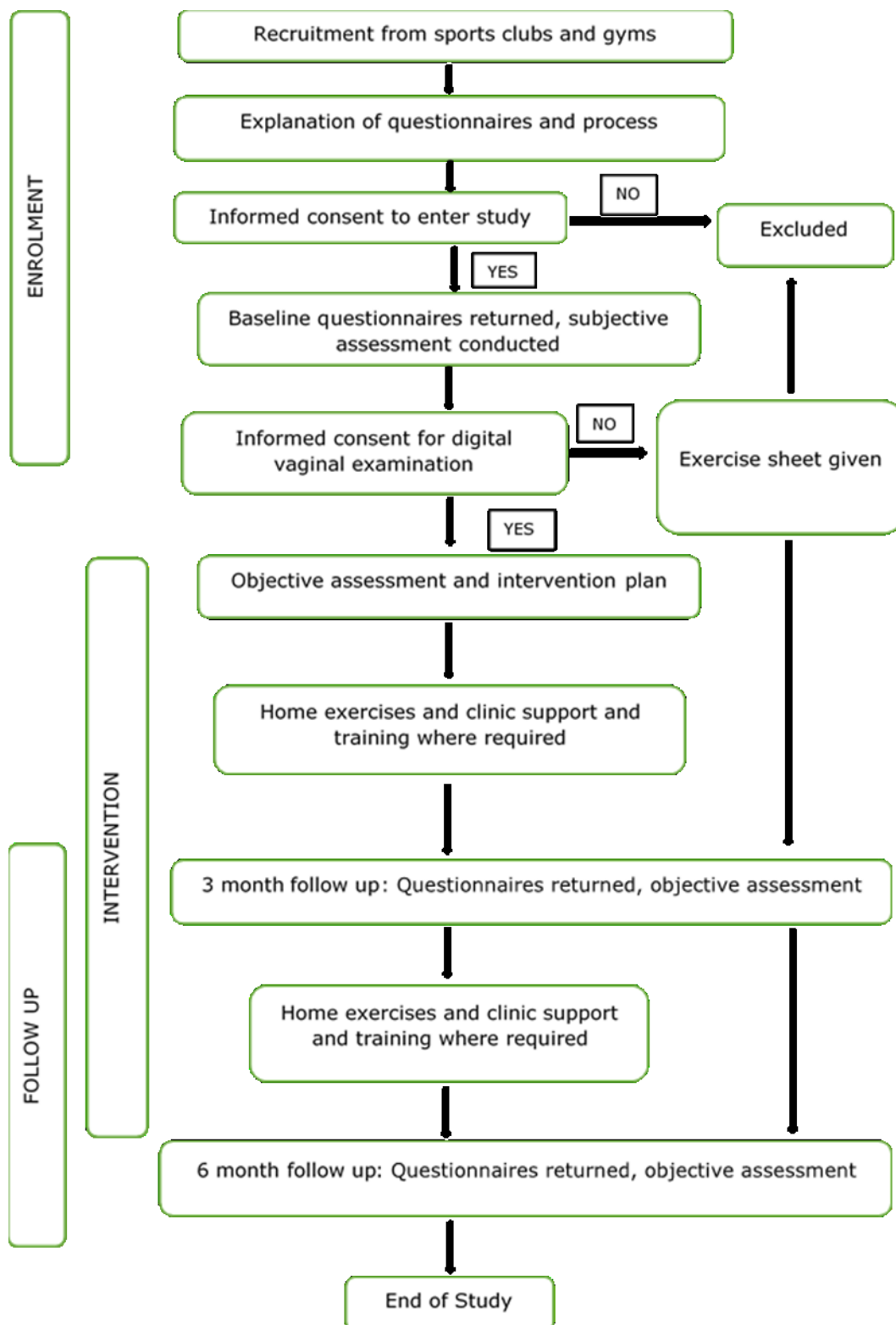


Figure 1 Flow chart of participants through Phase 2



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Compliance

Compliance will be assessed throughout phase 2. If the participant does not engage with the training and feedback then the investigator will re-address whether the participant still consents to completing the study.

Phase 3

Six to eight of the participants in phase 2 will be purposefully selected for a semi-structured interview for up to 30 minutes. This will discuss their experience of phase 2 of the study and any previous treatments they may have had for UI. It will explore their experiences of UI and the effects on their quality of life and sporting participation.

The interviews will be conducted face to face by a member of the research team. Digital audio-recordings will be transferred to a secure and password protected file on a dedicated web server at the University of Nottingham. Personal identifiers will be removed. The recording will then be deleted from the recording device. Anonymised recordings will be sent electronically to a transcribing service approved by the University of Nottingham.

Criteria for terminating the study

The study is unlikely to be terminated. Research data will not be destroyed but archived according to the archiving procedure detailed later.

ANALYSES

Methods

The data will be analysed by members of the research team.

Qualitative data will be analysed thematically. Nvivo software will be used to manage qualitative data.

Quantitative data will be analysed using descriptive statistics.

Analysis will take place on University of Nottingham computers and backed up on the University of Nottingham servers.

Sample size and justification

Phase 1

The sample size has been determined by the research team and relevant literature (Malterud et al., 2016) and is appropriate for this study.

Phase 2

As this is a feasibility study, the purpose is to provide estimates of recruitment and retention rates alongside the acceptability of the intervention therefore a formal



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sample size calculation is not required. Traditionally sample sizes between 24 and 50 are recommended for a feasibility study (Sim and Lewis, 2012), but consideration of the intensity and length of the proposed intervention also needs to be considered in deciding the sample size. This sample size will enable us to determine the feasibility of conducting a definitive trial.

Phase 3

The sample size has been determined by the research team and relevant literature as being of a sufficient size (Malterud et al., 2016).

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected in phases 1 or 3. Any adverse event data will be collected and reported.

It is again unlikely that any adverse events are likely to arise as part of the intervention in phase 2, as the intervention is standard physiotherapy practice for this issue, but any observation of unexpected pathology or trauma eg cancer, female genital mutilation or history of abuse during the subjective or objective parts of the assessment process will be discussed with the research team gynaecologist and appropriate advice taken.

ETHICAL AND REGULATORY ASPECTS

No significant ethical, legal or management issues are anticipated.

University research ethics committee approvals will be required and sought for the participants in Phase 1, 2 and 3.

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the University of Nottingham, Faculty of Medicine and Health Sciences, Research Ethics Committee (REC).

Should a protocol amendment be made that requires ethical approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the University REC. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.



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The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Study Forms

Each participant will be assigned a study identity code number, for use on study forms, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available).

Study forms will be treated as confidential documents and held securely in accordance with regulations

Study forms shall be restricted to those personnel approved by the Chief Investigator and recorded as such in the study records.



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Medical records will be stored securely and in accordance with good clinical practice for a time period of eight years from the last intervention. This is the recommended time for record retention by the Chartered Society of Physiotherapy who will be providing professional liability.

A letter documenting the outcomes of the assessments and intervention for each participant in phase 2 will be sent to the patients GP, with the participant's agreement, for recording within their medical records.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.

The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the study form.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. Intervention notes from Phase 2 will be filed during the intervention at the site that the participant has chosen from the two sites offered. A study form may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The study form and all source documents shall be made available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The study form will only collect the minimum required information for the purposes of the study. Study forms will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Information about the study in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.



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Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the professional indemnity provided by the CSP as the proposed interventions are covered within the researcher's scope of practice. There are no special compensation arrangements, but study participants may have recourse through the CSP.

STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator/Academic Supervisor shall carry out monitoring of study data as an ongoing activity.

Entries on study forms will be verified by inspection against the source data. A sample of study forms (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.



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The study documents held by the Chief Investigator shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

STATEMENT OF CONFIDENTIALITY

Individual participant personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by University of Nottingham representatives.

PUBLICATION AND DISSEMINATION POLICY

The study results will be submitted to academic journals and conferences. Participants will not be identified in any publications.

USER AND PUBLIC INVOLVEMENT

Membership of the study steering group will include two service user representatives.

STUDY FINANCES

FUNDING SOURCE

This study is funded by the University of Nottingham and the Medical Research Council.

PARTICIPANT STIPENDS AND PAYMENTS

Participants will not be paid to participate in the study. Travel expenses will not be reimbursed routinely but we may be able to support some participants with particular difficulties.



SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name) Dr Gillian Campbell

Signature: _____

Date: 28th March 2019 _____

Co-investigator: (name) Professor Avril Drummond

Signature: _____



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REFERENCES

- ALVES, J. O., LUZ, S. T. D., BRANDAO, S., DA LUZ, C. M., JORGE, R. N. & DA ROZA, T. 2017. Urinary Incontinence in Physically Active Young Women: Prevalence and Related Factors. *Int J Sports Med*, 38, 937-941.
- AW, H. C., RANASINGHE, W., TAN, P. H. M. & O'CONNELL, H. E. 2017. Overactive pelvic floor muscles (OPFM): improving diagnostic accuracy with clinical examination and functional studies. *Translational Andrology and Urology*, 6, S64-S67.
- BO, K. 2004. Urinary incontinence, pelvic floor dysfunction, exercise and sport. *Sports Med*, 34, 451-64.
- BO, K., BRATLAND-SANDA, S. & SUNDGOT-BORGEN, J. 2011. Urinary incontinence among group fitness instructors including yoga and pilates teachers. *Neurourol Urodyn*, 30, 370-3.
- BO, K., TALSETH, T. & HOLME, I. 1999. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *Bmj*, 318, 487-93.
- BROWN, W. J. & MILLER, Y. D. 2001. Too wet to exercise? Leaking urine as a barrier to physical activity in women. *Journal of Science and Medicine in Sport*, 4, 373-378.
- CARLS, C. 2007. The prevalence of stress urinary incontinence in high school and college-age female athletes in the midwest: implications for education and prevention. *Urol Nurs*, 27, 21-4, 39.
- CARVALHAIS, A., NATAL JORGE, R. & BØ, K. 2018. Performing high-level sport is strongly associated with urinary incontinence in elite athletes: a comparative study of 372 elite female athletes and 372 controls. *British Journal of Sports Medicine*, 52, 1586-1590.
- COOPER, J., ANNAPPA, M., QUIGLEY, A., DRACOCARDOS, D., BONDILI, A. & MALLIN, C. 2015. Prevalence of female urinary incontinence and its impact on quality of life in a cluster population in the United Kingdom (UK): a community survey. *Prim Health Care Res Dev*, 16, 377-82.
- DA ROZA, T., DE ARAUJO, M. P., VIANA, R., VIANA, S., JORGE, R. N., BO, K. & MASCARENHAS, T. 2012. Pelvic floor muscle training to improve urinary incontinence in young, nulliparous sport students: a pilot study. *Int Urogynecol J*, 23, 1069-73.
- DANFORTH, K. N., TOWNSEND, M. K., LIFFORD, K., CURHAN, G. C., RESNICK, N. M. & GRODSTEIN, F. 2006. Risk Factors for Urinary Incontinence among Middle-aged Women. *American journal of obstetrics and gynecology*, 194, 339-345.
- DUMOULIN, C., LEMIEUX, M.-C., BOURBONNAIS, D., GRAVEL, D., BRAVO, G. & MORIN, M. 2004. Physiotherapy for Persistent Postnatal Stress Urinary Incontinence: A Randomized Controlled Trial. *Obstetrics & Gynecology*, 104, 504-510.
- FERREIRA, S., FERREIRA, M., CARVALHAIS, A., SANTOS, P. C., ROCHA, P. & BROCHADO, G. 2014. Reeducation of pelvic floor muscles in volleyball athletes. *Revista da Associação Médica Brasileira*, 60, 428-433.
- FULTZ, N., GIRTS, T., KINCHEN, K., NYGAARD, I., POHL, G. & STERNFELD, B. 2005. *Prevalence, management and impact of urinary incontinence in the workplace*.



POsITive

- HAYLEN, B. T., DE RIDDER, D., FREEMAN, R. M., SWIFT, S. E., BERGHMANS, B., LEE, J., MONGA, A., PETRI, E., RIZK, D. E., SAND, P. K. & SCHAER, G. N. 2010. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *International Urogynecology Journal*, 21, 5-26.
- JACOME, C., OLIVEIRA, D., MARQUES, A. & SA-COUTO, P. 2011. Prevalence and impact of urinary incontinence among female athletes. *Int J Gynaecol Obstet*, 114, 60-3.
- KUH, D., CARDOZO, L. & HARDY, R. 1999. Urinary incontinence in middle aged women: childhood enuresis and other lifetime risk factors in a British prospective cohort. *Journal of Epidemiology and Community Health*, 53, 453-458.
- MALTERUD, K., SIERSMA, V. D. & GUASSORA, A. D. 2016. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qualitative Health Research*, 26, 1753-1760.
- MCKENZIE, S., WATSON, T., THOMPSON, J. & BRIFFA, K. 2016. *Stress urinary incontinence is highly prevalent in recreationally active women attending gyms or exercise classes.*
- MENEZES, E. C., VIRTUOSO, J.F., MAZO, G.Z. 2015. Older women with urinary incontinence present less physical activity level than usual. *Revista Brasileira de Cineantropometria e Desempenho Humano*, 17, 612-620.
- NICE 2013. Urinary incontinence in women: the management of urinary incontinence in women. London: National Institute for Health and Care Excellence.
- NILSSON, M., LALOS, A. & LALOS, O. 2009. The impact of female urinary incontinence and urgency on quality of life and partner relationship. *Neurourol Urodyn*, 28, 976-81.
- NYGAARD, I., GIRTS, T., FULTZ, N. H., KINCHEN, K., POHL, G. & STERNFELD, B. 2005. Is urinary incontinence a barrier to exercise in women? *Obstet Gynecol*, 106, 307-14.
- SIM, J. & LEWIS, M. 2012. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol*, 65, 301-8.
- WEISS, J. M. 2001. Pelvic Floor Myofascial Trigger Points: Manual Therapy for Interstitial Cystitis and the Urgency-Frequency Syndrome. *The Journal of Urology*, 166, 2226-2231.